UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/556,178	04/20/00	BANDMAN O	PF-417-US

HM22/0813

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EXAMINER	
STRZELECKA,T	
ART UNIT	**PAPER NUMBER**
1656	5

DATE MAILED: 08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/556,178	Applicant(s) BANDMAN ET AL.	
	Examiner Teresa E Strzelecka	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *3-15 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and SEQ ID NO:1 in Paper No. 3 is acknowledged. The traversal is on the ground(s) that:

(A) Claims 1, 2, 16 and 17 are drawn to polypeptides comprising three sequences with SEQ ID Nos 1, 3 and 5, and if no prior art is found over which SEQ ID NO: 1 can be rejected, the search should include SEQ ID NO: 3 and 5;

(B) Group III, drawn to antibodies to the polypeptides could be examined together with Group I without an undue burden on the Examiner,

(C) Group V, the methods of using the polypeptides, should be examined together with Group I, since in the case the product (polypeptide) is allowed, the method claims would be rejoined.

This is not found persuasive because:

(a) As stated by Applicants in the third paragraph on page 4, in the case of a Markush-type claim including independent and distinct inventions the examiner may require a provisional election of single species, "This clearly applies in the present case". Applicants are advised that the sequences presented in claims 1, 2, 16 and 17 are considered as distinct and independent inventions, not species, since SEQ ID NO: 1, 3 and 5 describe three different proteins with different structures and modes of action.

(b) With respect to point (B), contrary to Applicants assertion that the search of prior art in regard to Group I will reveal whether any prior art exists for the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to the anticipation of the invention, and therefore search for references which would anticipate or render

obvious the polypeptides of Group I would be very different from the search for references which would anticipate or render obvious the antibodies of Group III.

(c) With respect to point (C), see the argument for point (B). In case the polypeptides of Group I are found allowable, claims of Group V can be rejoined with claims of Group I.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-15 and 18-20 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions II-V, there being no allowable generic or linking claim. Claims 1, 2, 16 and 17 will be examined to the extent that they read on SEQ ID NO: 1. Applicant timely traversed the restriction (election) requirement in Paper No. 3.

35 U.S.C. 101 Utility Rejections

3. 35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Definitions: [UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

"Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A

credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the specific and substantial tests (see below).

"Specific Utility" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a specific or substantial utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial asserted utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility

that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

4. Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed polypeptide compound (VTP-1, SEQ ID NO: 1) is not supported by a specific asserted utility because the disclosed uses of the protein are not specific and are generally applicable to a wide variety of proteins. The specification states that the nucleic acid compounds encoding VTP-1 may be useful as hybridization probes, PCR primers, in microarray assays, gene mapping, for therapeutic purposes as antisense ologonucleotides, parts of expression vectors and for gene therapy (page 32 lines 10-30; page 33; page 34, lines 1-22; page 38, line 31; page 39-44; page 45, lines 1-19). Similarly, protein may be used for detection of expression, antibody production, Western blots, and therapeutic application against a wide range of conditions (disorders associated with increased apoptosis, cell proliferation, inflammation) (page 28-30; page 31, lines 1-9; page 38, lines 13-30; page 45, lines 20-30; page 46, lines 1-7). These are non-specific uses that are applicable to nucleic acids and/or proteins in general and not particular or specific to the nucleic protein being claimed.

Further, the claimed protein compound is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound such that another non-asserted utility would be well established for the compounds.

It is noted that applicants have listed a sequence which is known in the prior art (human homologoue of a yeast vacuolar protein sorting vps45) and which has a 97.8% sequence similarity to a claimed sequence (VPT-1). Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in

limited specific cases: Gerhold et al. (BioEssays, Volume 18, Number 12, pages 973-981, 1996); Wells et al. (Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550, 1997); and Russell et al. (Journal of Molecular Biology, Volume 244, pages 332-350, 1994).

In addition, the function of human vps45 protein is not known. Pevsner et al. (Gene, vol. 183, pp. 7-14, 1996) teaches that human vps45 homologue may participate in vesicular trafficking between the Golgi and the lysosome and may interact with syntaxin homologues which potentially mediate specific stages of vesicle trafficking, but they conclude that the function of this protein is unknown. This protein does not bind to the known syntaxins (page 7; page 8, second paragraph; Fig. 3 and Table 1; page 13, second and third paragraphs). Therefore, it is not possible to ascertain at present what is the utility of VTP-1, and thus, what disorders may be treatable with this polypeptide.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 16 and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 (b) is indefinite because of the following limitations "a naturally-occuring amino acid sequence having at least 90% sequence identity to...". Applicants do not describe what is encompassed by the term "naturally-occuring". The term "having... sequence identity" does not clearly define the scope of the claim.

B) Claim 1 (c) is indefinite because of the limitation "a biologically-active fragment of an amino acid sequence...". It is unclear which amino acids form biologically-active fragments of SEQ ID NO: 1 or how the activity would be determined.

C) Claim 1 (d) is indefinite because of the limitation "an immunogenic fragment of an amino acid sequence...". It is unclear which amino acids form immunogenic fragments of SEQ ID NO: 1.

D) Claim 2 is indefinite because of the limitation "...having a sequence...". The term "having a sequence" does not clearly define the scope of the claim.

E) Claim 17 is indefinite because of the limitation "...polypeptide has an amino acid sequence...". The term "has a sequence" does not clearly define the scope of the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Pevsner et al. (EMBL sequence with accession number ACQ15715, "Vacuolar protein sorting homolog h-vps45", November 1, 1996).

ACQ15715 has 97.8% amino acid sequence identity to SEQ ID NO: 1 (VTP-1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
August 9, 2001 TS

Kenneth R. Horlick, Ph.D.
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PRIMARY EXAMINER
GROUP 1600
8/10/01